DATE 30 Sep 03

USAMMDA INFORMATION PAPER

PRODUCT: HEPATITIS E VIRUS (HEV) VACCINE

DESCRIPTION: The HEV vaccine is designed to provide protection against infection with and disease caused by the HEV. The HEV vaccine is a recombinant vaccine that consists of a purified polypeptide produced in insect cells infected with recombinant baculoviruses. It is formulated with an aluminum salt adjuvant. Hepatitis E is endemic in many regions of the world with U.S. national security strategic interests. The virus is transmitted primarily by the fecal-oral route; drinking fecally contaminated water is the most common mode of transmission. The illness often occurs two to six weeks after infection and results in protracted convalescence lasting several weeks to months. In some cases, infection results in severe rapidly progressing disease that ends in death due to liver failure. The case-fatality rate is approximately two percent in men and non-pregnant women and up to 20 percent during the third trimester of pregnancy. The highest incidence of HEV infection occurs in young adults (of military age). Approximately 97 percent of American adults are susceptible to HEV infection. Outbreaks of HEV infection have been identified in India, Myanmar (Burma), Iran, Bangladesh, Ethiopia, Nepal, Pakistan, central Asian Republics of the former Soviet Union, Algeria, Libya, Somalia, Mexico, Indonesia and China. Non-immune Service members deployed to endemic regions are at high risk, and the resultant disease could seriously disrupt the conduct of a military mission.

PROGRAM RELEVANCE to the ARMY: This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: “Shape the Security Environment,” “Forcible Entry Operations,” “Sustained Land Dominance” and “Support Civil Authorities” by protecting U.S. Forces against infection with the HEV virus. The HEV vaccine will enhance the survivability and sustainability of U.S. Forces in regions of the world where HEV is endemic. In addition, this product supports Future Operational Capability MD97-007 (Preventive Medicine).

ISSUES/ ACTIONS:

- A number of significant protocol amendments were implemented by the investigative team without formal review and approval by cognizant institutional review boards. Though none of the changes increased risk of harm to study volunteers, they did result in extensive protocol deviations. The investigative team will prepare memoranda for the study regulatory file documenting all deviations. An amendment encompassing all changes to the protocol not reviewed and approved by cognizant institutional review boards has been drafted and is under review.
- Study visit eight (subject encounter 8; the last follow-up visit post vaccination) cannot be conducted successfully according to the schedule contained in the currently approved verson of the study protocol. Without amendment, numerous additional protocol deviations will accrue. A separate single-item amendment to correct the schedule for visit eight will be submitted to the institutional review boards and the sponsor for expedited review and approval.

BPL #: 385
DA PROJECT/TASK: Infectious Diseases
PE/PROJ 643807.808ND
MAMP RANK: 14/36
ARMY ORD: Draft

SCHEDULE:

MS I	4QFY99
MS B	1QFY04
MS FRP	2QFY07

For additional information, contact: Pharmaceutical System Division, DSN 343-2051, Comm. 301-619-2051